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Docket No. ORT-1373

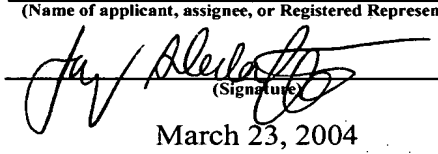
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	SHANGOLD et al.
Serial No.	:	09/782,420
Filed	:	02/13/2001
Title	:	TRIPHASIC ORAL CONTRACEPTIVE
Art Unit	:	1617
Examiner	:	Travers, Russell S.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 23, 2004
(Date of Deposit)

Joseph S. Kentoffio
(Name of applicant, assignee, or Registered Representative)


(Signature)

March 23, 2004
(Date of Signature)

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

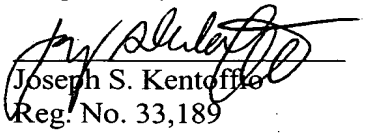
APPEAL BRIEF TRANSMITTAL

Dear Sir:

Enclosed is an Appeal Brief for the above-referenced patent application.

Please charge Deposit Account No. 10-0750/ORT-1373/JSK in the name of Johnson & Johnson for the cost of filing this Appeal Brief. Three copies of this Transmittal are enclosed.

Respectfully submitted,



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DATE: March 23, 2004

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ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 1.192

Dear Sir:

This is an appeal from the Final Rejection of October 21, 2003, a Notice of Appeal having been received by the USPTO on January 23, 2004. Appellants' Brief is being submitted on March 23, 2004.

The fees required under 37 C.F.R. § 1.17(f), and any required petition for extension of time for filing this brief and fees therefore, are addressed in the accompanying TRANSMITTAL OF APPEAL BRIEF.

Pursuant to 37 C.F.R. § 1.192(a), this brief is transmitted in triplicate.

REAL PARTY IN INTEREST

The real party in interest of the above-referenced patent application is Ortho-McNeil Pharmaceutical, Inc., having a principal place of business at Route 202, Raritan, NJ 08869.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

STATUS OF CLAIMS

Claims 18-22 stand rejected under 35 U.S.C. § 103(b), as being unpatentable over EP 0 491 415A1 (hereinafter "Bergink") in view of Darney et al. and Alapiessa et al.

STATUS OF AMENDMENTS

The claims stand amended as set forth in the Response To Office Action filed on January 29, 2003.

SUMMARY OF THE INVENTION

The present invention relates to a contraceptive method comprising the administration of a triphasic regimen of ethinyl estradiol and desogestrel. In the first phase of the regimen 0.100 mg of desogestrel and 25 μg ethinyl estradiol are administered daily for a period of 5-8 days. In a second phase, 0.125 mg of desogestrel and 25 μg ethinyl estradiol are administered daily for a period of 7-11 days, and in a third phase, 0.150 mg of desogestrel and 25 μg ethinyl estradiol are administered daily for a period of 3-7 days. Following these three phases, there is a period of 4-8 days free of ethinyl estradiol and desogestrel administration. The invention also provides an oral triphasic contraceptive unit comprising 21 separate dosage units adapted for successive daily oral administration to administer the above-described regimen.

STATEMENT OF ISSUES

Whether Claims 18-22 are obvious over Bergink in view of Darney et al and Alapiessa et al.

GROUPING OF CLAIMS

For the purposes of this Appeal, all of the pending claims 18-22 stand or fall together.

ARGUMANTS

Claims 18-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bergink in view of Darney et al. and Alapiessa et al. The Examiner argues that Bergink teaches triphasic oral contraceptive methods, compositions and units substantially similar to the claimed invention. The Examiner admits, however, that Bergink fails to disclose the particular contraceptive hormones of the instant claims and the claimed dosage levels of those hormones. The Examiner relies on Alapiessa et al to teach the combination of ethinyl estradiol and desogestrel in a 21-day regimen, and on Darney et al for teaching the claimed level of ethinyl estradiol. Applicants submit that the Examiner's rejection based on the combination of these three references is not well founded and should be overturned.

With respect to Bergink, applicants note that this reference teaches a phasic contraceptive regimen in which the dosage of ethinyl estradiol (EE) is varied over the various phases. In particular, Bergink teaches a first phase in which the dosage of EE is 25 micrograms, and second and third phases in which the dosage of EE is lowered to 20 micrograms. This is in contrast to the present invention wherein the dosage of EE is kept constant at 25 micrograms over all three phases of the claimed regimen. Furthermore, as noted by the Examiner, Bergink teaches a 24-day cycle divided into three eight-day phases of hormone administration followed by a four day pill-free period or a four day period of progestin-only administration. Again, this is in contrast to the claimed method which includes 21 days of phasic hormone administration followed by a period which is free of hormone administration.

The Examiner argues that altering the active ingredient dosage level to effect optimal contraceptive benefit would be obvious based on the teachings of Darney. However, Darney teaches that cycle control increases and rates of breakthrough bleeding and spotting are reduced as the estrogen content increases. Darney teaches that cycle control is maximized with EE dosages of 30-35 μg or even a 50 μg. Darney goes even further when he recommends supplementing regular OC use with additional conjugated estrogen or estrone sulfate.

Accordingly, even if one skilled in the art were to combine Bergink and Darney as suggested by the Examiner, the result would be a phasic contraceptive providing an EE

dosage substantially higher that that recited in the instant claims. Moreover, based on the teachings of Bergink, the EE dosage would, itself, be phased at this much higher level, since Bergink teaches varying the EE dosage over the various phases of the regimen.

The Examiner argues that applicants have failed to provide data establishing the unexpected results achieved by the claimed invention. To this point, applicants make reference to the data contained in the tables and the examples set forth in the specification. These data show that good cycle control is maintained with a triphasic regimen utilizing a constant daily dosage of 25 micrograms of ethinyl estradiol. While the particular regimen referred to is a triphasic combination of norgestimate and ethinyl estradiol, this does not alter the fact that the degree of cycle control reported at a 25 μg daily dose of EE is completely unexpected in view of Darney's teaching that good cycle control is maximized where the daily dosage of estrogen is maintained at 30 to 50 micrograms. The good cycle control provided by applicants' low daily EE dosage is even more unexpected in view of Darney's suggestion that patients supplement regular OC use with additional conjugated estrogen or estrone sulfate.

The Examiner cites Alapiessa et al. for the teaching of a 21-day cycle. However, a person skilled in the art would not be motivated by the teachings of Alapiessa to alter the 24-day cycle taught by Bergink to the claimed 21-day regimen, since Alapiessa nowhere teaches or suggests a phasic contraceptive regimen wherein the EE dosage remains constant over the entire regimen while the progestin dosage is varied in discrete phases. Alapiessa teaches either monophasic regimens, wherein the EE and progestin dosages remain constant over the entire regimen, or phasic regimens wherein there is an initial phase of estrogen-only administration followed by a phase in which estrogen and progestin are administered together.

Applicants submit that the Examiner is using the claimed invention to piece together selected disclosures of the three cited references in order to render the claimed invention obvious. Such hindsight reconstruction of the claimed invention is not permissible and cannot be relied on to support a rejection under § 103(a). In re Fritch, 23 USPQ 2d 1780, 1784 (Fed. Cir. 1992).

In view of the foregoing, appellants request that the Examiner's Final Rejection be overturned and that this application be passed to allowance at the earliest possible date.

Please charge the fee of $330.00 required under 37 C.F.R § 1.17(c), any deficiency in this fee and any other fees that may be required in connection with the filing of appellants' Appeal Brief to Deposit Account No. 10-0750/ORT-1373/JSK.

Appellants' Appeal Brief is being filed in triplicate.

Respectfully submitted,

By: _____
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Dated: March 23, 2004

APPENDIX OF CLAIMS

18. (New) A method of contraception which comprises administering for 21 successive days to a female of child bearing age a combination of ethinyl estradiol and desogestrel in a contraceptively effective daily dosage in which there is a first phase of 5-8 days wherein the combination comprises an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.100 mg; followed by a second phase of 7-11 days wherein the combination comprises an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.125 mg; followed by a third phase of 3-7 days wherein the combination comprises an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.150 mg; and followed by 4-8 days free of estrogen and desogestrel administration.

19. (New) The method of claim 18, wherein the ethinyl estradiol and the desogestrel are administered orally and the period of each phase is seven days.

20. (New) The method of claim 1, wherein the ethinyl estradiol and the desogestrel are administered in admixture.

21. (New) A triphasic oral contraceptive unit having 21 separate dosage units adapted for successive daily oral administration comprising: 5-8 dosage units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.100 mg as a first phase; followed by 7-11 dosage units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.125 mg as a second phase; followed by 3-7 dosage units containing, in admixture with a pharmaceutically acceptable carrier, an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.150 mg as a third phase; and optionally containing 4-8 additional dosage units free of ethinyl estradiol and desogestrel.

22. (New) The contraceptive unit according to claim 10, wherein the dosage units are in the form of tablets.